

OLESTRA AND ITS IMPACT ON NUTRIENT DATABASES

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ABSTRACT

This presentation will provide an update on olestra (Olean®), Procter & Gamble's non-caloric fat replacer. The update will provide answers to such questions as: What is olestra and how is it made? In what foods can olestra be used and what impact does olestra have on the caloric density of such foods? How much olestra will people eat? What is the basis for fat-soluble vitamin addition? What impact will olestra foods containing added fat-soluble vitamins have on the nutrition information panel? What analytical methods are needed to distinguish olestra from digestible triglycerides for purposes of nutrition labeling? What is the information label that will appear on olestra foods and what forms the basis for this labeling requirement?

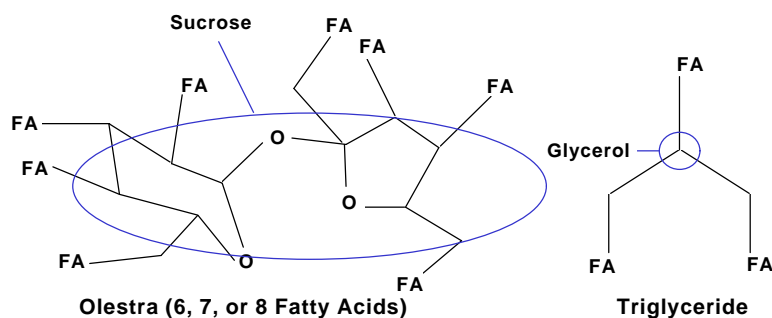
1. Presentation Overview

- Olestra - Structure, Manufacture and Safety
- Categories of Approved Food Use
- Caloric Density Implications
- Estimated Intakes
- Vitamin Addition - Rationale and Nutrient Panel Impact
- NLEA Analytical Method Considerations
- Information label - Carotenoid and Digestive Effects

2. Definition of Olestra

CFR 172.867(a)

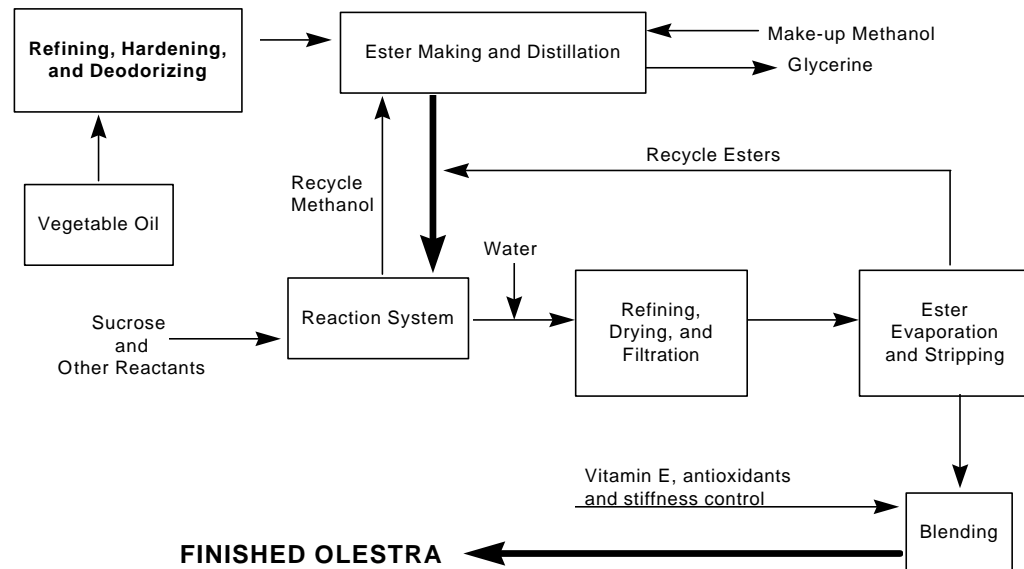
"Olestra is a mixture of octa-, hepta- and hexa-esters of sucrose with fatty acids derived from edible fats and oils or fatty acid sources that are generally recognized as safe or approved for use as food ingredients. The chain lengths of the fatty acids are no less than 12 carbon atoms."

Structural Model of Olestra

FA = Fatty Acid Side Chain

3. Manufacture of Olestra

How Is Olestra Made



4. Safety of Olestra

- FAP > 150,000 pages (about 300 volumes)
- More than 100 studies in 7 animal species show that olestra
 - Is not absorbed
 - Is not toxic
 - Does not cause cancer, birth defects or adverse reproductive effects
 - Does not affect gastrointestinal structure or function
 - Does not affect the absorption of medicines
- Olestra was tested in 98 human studies:
 - 43 were tightly controlled clinical studies in more than 4300 men, women and children up to 16 weeks in duration
 - 55 were human preference or sensory studies in more than 16,000 people with duration measured in years

Testing covered the general population, people with diabetes, obese people, those with GI disease and people with elevated serum cholesterol

- Amount of olestra consumed ranged up to 90 g/d
- No harmful effects were seen
- Clinical studies verified that olestra does not affect the absorption or efficacy of drugs

5. Environmental Assessment

- Olestra is safe for the environment:
 - Is effectively removed and has no adverse effects on wastewater treatment facilities
 - Major exposure compartment in environment will be soil
 - Biodegrades in the environment and does not accumulate
 - Is non-toxic to terrestrial, aquatic and benthic organisms
 - Has no adverse effect on soil physical properties

6. Versatility of Olestra

Fat Replacer	Dairy	Spreads	Dressings	Baking	Frying
Protein-based	✓	✓	✓		
Carbohydrate-based	✓	✓	✓	✓	
Fat-based, e.g., Olean	✓	✓	✓	✓	✓

7. The Olestra Regulation

CFR 172.867(c)

"Olestra may be used in place of fats and oils in prepackaged ready-to-eat savory (i.e., salty or piquant but not sweet) snacks. In such foods, the additive may be used in place of fats and oils for frying or baking, in dough conditioners, in sprays, in filling ingredients, or in flavors."

8. Categories of Approved Food Use

- Savory snacks under this regulation will include such products as:
 - Plain and flavored:
 - Potato chips
 - Tortilla chips
 - Corn chips
 - Cheese puffs/curls
 - Crackers (soda, plain, flavored and filled)

9. Current Test Market Activity

- Three cities:
 - Eau Claire, WI
 - Cedar Rapids, IA
 - Grand Junction, CO
- Four Frito-Lay Products:
 - Lays, Ruffles, Doritos, Tostitos
 - About 7 Stock Keeping Units (SKU)

10. Fat and Calorie Reduction in 1 oz. of Snack Foods

	Fat, grams	Calories, kcal
Potato chips:		
• current	10	160
• olestra	0	70
Tortilla chips:		
• current	7	140
• olestra	1	90

FIGURE. Example of Nutrition Facts Label for Olestra Containing Foods

Nutrition Facts	
Serving Size 1 oz (28 g about 22 chips)	
Servings Per Container 14	
Amount Per Serving	
Calories 70	Calories from Fat 0
% Daily Value*	
Total Fat 0 g	0%
Saturated Fat 0 g	0%
Cholesterol 0 mg	0%
Sodium 180 mg	8%
Potassium 400 mg	
Total Carbohydrate 16 g	5%
Protein 1 g	
Vitamin C 10%	Iron 2%

Ingredients: Potatoes, Olestra (Olean Brand), Salt, alpha-Tocopheryl Acetate (Vitamin E), Tocopherols (to protect flavor), Vitamin A Palmitate, Vitamin K₁ and Vitamin D.

11. How Much Will People Eat?

- Intake of olestra for the total population of savory snack consumers at the 90th %tile is estimated at about 18 g/day on eating days and about 7 g olestra per day on a lifetime daily average basis
- Intake was determined using the MRCA method with conservative assumptions

Intakes Estimated By The MRCA Menu Census Survey

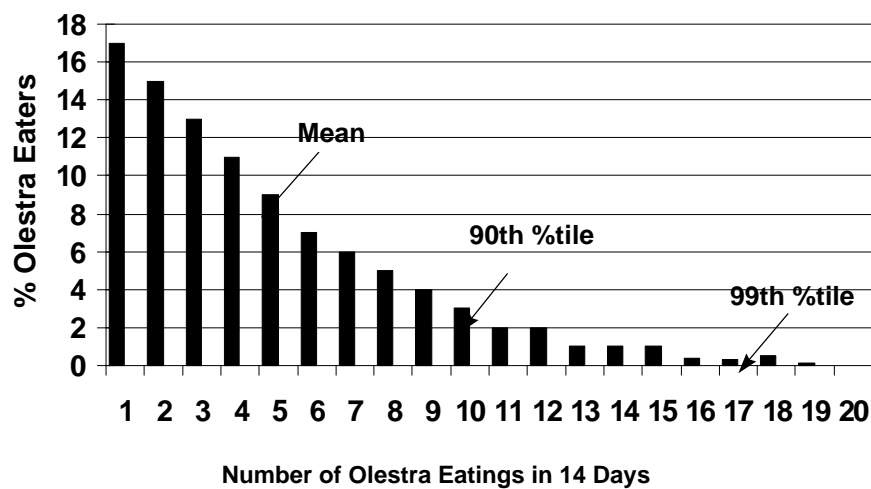
- The intake survey includes 2,000 households and 5,000 subjects annually
- This survey, used by the FDA,
 - is demographically balanced by age, gender, race and income
 - is geographically balanced
 - tracks the intake of food and drink consumed at home and away from home for 14 days
 - runs continuously throughout the year
- We used conservative assumptions which will result in an exaggeration compared to what actual population intake will be:
 - 100% of savory snacks are made with olestra
 - Then increased intake by 10%

12. Olestra Consumption

Olestra Intake on Eating Days (grams/day)

Group	Savory Snack Eaters	
	Mean	90 th %tile
Total Population of Eaters	10.2	18.3
2-5 yr (males and females)	8.4	13.5
13-17 yr (males)	16.5	23.9
≥ 65 (males)	7.5	16.2

Frequency of Olestra (snack) Consumption (*All Ages*)



Olestra 14-Day Average Intake (grams/day)

Group	Savory Snack Eaters	
	Mean	90 th %tile
Total Population of Eaters	3.1	6.9
2-5 yr (males and females)	3.0	6.4
13-17 yr (males)	4.7	10.9
≥ 65 (males)	2.4	5.4

13. The Olestra Regulation

CFR 172.867(d)

"To compensate for any interference with absorption of fat-soluble vitamins, the following vitamins shall be added to foods containing olestra:"

- 1.9 milligrams α -tocopherol equivalents per gram olestra (e.g., 2.07 mg d - α -tocopheryl acetate)
- 51 retinol equivalents per gram olestra (as retinyl acetate or retinyl palmitate) (e.g., 93 μ g retinyl palmitate)
- 12 IU vitamin D per gram olestra (e.g., 300 ng vitamin D)
- 8 micrograms vitamin K₁ per gram olestra

14. Comparison of Vitamin Compensation Levels With Foods In the Diet

<u>Vitamin</u>	<u>RDI of Vitamin in a 1 oz Serving</u>	<u>Foods with Similar Amounts of Vitamin</u>
A	0.3	1/3 serving of fortified breakfast cereal
D	0.1	1/3 cup milk
E	0.7	2 Tbs mayonnaise
K	1.0	1/6 cup of broccoli

15. NLEA Analytical Method Considerations

- Existing methods will over-estimate fat content in olestra foods because olestra will be extracted with the fat
- An AOAC Peer-Verified Method has been developed to separate dietary fat from olestra (PVM 4:1995, pp. 1-29)
- This method allows compliance with the U.S. NLEA guidelines for "fat-free" and "low-fat"
- Method overview:
 - CHCl₃ extraction
 - Lipase hydrolysis yielding free fatty acids (FFA) and intact olestra
 - FFA precipitation as Ca soaps
 - Olestra removal with hexane extraction
 - FFA formation via acidification
 - Methyl ester formation
 - Quantification by gas chromatography
- Recovery 101 \pm 6%

16. The Olestra Information Label - Carotenoid and Digestive Effects

CFR 172.867(e)(1)

"The label of a food containing olestra shall bear the following statement in the manner prescribed in paragraph (e)(2) of this section (interim proposal):

This Product Contains Olestra. Olestra may cause abdominal cramps and loose stools. Olestra inhibits the absorption of some vitamins and other nutrients. Vitamins A, D, E and K have been added."

17. Key Technical Facts - Digestive Effects

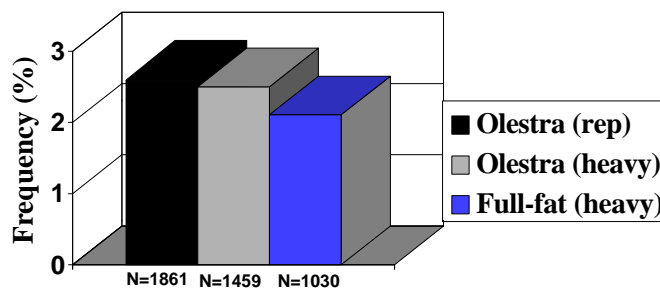
Most consumers will not experience digestive changes (e.g., change in stool consistency, bloating) when eating olestra snacks and for those that do, these will be no different than those that can occur with common foods

The FDA, the Food Advisory Committee, P&G and leading gastroenterologists concluded that these effects do not represent a potential for harm

The “oil-loss” reported when some people ate large amounts of early versions of olestra was addressed through product modifications before P&G filed the olestra FAP

- Clinical testing confirms that this has been resolved
- These clinical results form the basis for the olestra stiffness specification (at least 50 kilopascals/sec)

Reports of digestive effects at snack consumption levels, including heavy snackers, are similar as for current snacks based on voluntary comments



The increased reports of digestive changes by people in clinical studies eating exaggerated amounts (up to 32 grams per day) under unrealistic conditions (eaten with every meal for 56 consecutive days) are:

- The same kind of effects reported when subjects consume ordinary fat
- No more severe when larger amounts of olestra are eaten or when eating is maintained for weeks at a time

18. Key Technical Facts - Carotenoids

Olestra can reduce the absorption of some fat-soluble food components (e.g., carotenoids) when consumed at about the same time

The FDA, the Food Advisory Committee, P&G and leading nutrition researchers concluded that olestra will not adversely impact components of fruits and vegetables that may reduce the risk of chronic disease

This conclusion was based on the following three factors:

- Olestra does not affect most components in fruits and vegetables
- The effect of olestra on carotenoids is small and well within normal variations in carotenoid levels and is similar to the effect from other common foods
- There is no consensus on a carotenoid role in disease prevention

19. Impact of Olestra On Other Components of the Diet

- Olestra will not affect the other substances in fruits and vegetables that are associated with a health benefit
 - Antioxidants: Olestra will have no impact on water-soluble vitamin C. Any impact on vitamin E will be offset by vitamin E addition.
 - Other Substances: Olestra will have no impact on fiber or water-soluble folate. Any impact on vitamin A will be offset by vitamin A addition.

20. Phytochemicals In the Diet Are Not Lipophilic Enough To Be Affected By Olestra

Terpenoids
Flavonoids
Polyphenols
Isothiocyanates
Indoles
Organosulfides

21. Key Technical Facts - Carotenoids -

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22. Results of a Three-Part Carotenoid Research Program

<u>Test</u>	<u>Reduction in b-Carotene Status</u>
Extreme Case	60%
Exaggerated Case	25%
REALISTIC CASE	6-10%

23. Many Factors Can Potentially Reduce the Uptake of Dietary Components

<u>Interaction</u>	<u>% Reduction at a Meal</u>
Fat-free meal and <i>b</i> -carotene	100
Fiber and <i>b</i> -carotene	58
<i>b</i> -Carotene supplement and lutein	50
Cholesterol-lowering agents	30-70
Milk or cheese and iron	50
Tea or red wine and iron	60
Calcium supplement and zinc	85

24. Key Technical Facts - Carotenoids

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 - The effect of olestra on carotenoids is small and well within normal variations in carotenoid levels and is similar to the effect from other common foods
 - There is no consensus on a carotenoid role in disease prevention
- Diets high in fruits and vegetables are recognized in observational clinical trials to provide a health benefit
- This does not establish a cause-and-effect health benefit role for carotenoids *per se*
- Such data are confounded because diets high in fruits and vegetables may confer a health benefit because such a diet:
 - is low in fat, iron and calories
 - is high in vitamin C, vitamin E and fiber
 - may be associated with regular exercise and lack of smoking
- Intervention trials support the conclusion that *b*-Carotene is not protective against chronic disease
- No Consensus for Role of Carotenoids In Prevention of Chronic Disease
 - 1994 “Antioxidant Vitamins and b-Carotene in Disease Prevention”, sponsors included the National Cancer Institute and the National Heart, Lung and Blood Institute.
 - 1993 “Antioxidant Nutrients and Cancer and Cardiovascular Disease”, FDA Conference.
 - 1993 “Role of Antioxidants on Health”, the International Life Science Institute.
 - 1987 UK Committee on Medical Aspects of Food Policy